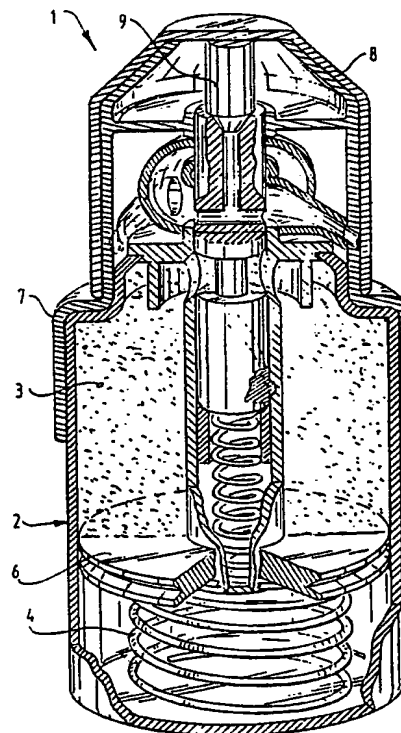




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<b>(21) International Application Number:</b> PCT/EP91/01884 <b>(22) International Filing Date:</b> 26 September 1991 (26.09.91)  <b>(30) Priority data:</b> 9002103 26 September 1990 (26.09.90) NL 9101245 15 July 1991 (15.07.91) NL 9101593 20 September 1991 (20.09.91) NL  <b>(71) Applicants (for all designated States except US):</b> PHARBITA B.V. [NL/NL]; Badhuisweg 1, NL-1506 PA Zaandam (NL). RAYCAP B.V. [NL/NL]; Kerkstraat 18, NL-5253 AP Nieuwkuyk (NL).  <b>(72) Inventors; and</b> <b>(75) Inventors/Applicants (for US only) :</b> ZANEN, Pieter [NL/NL]; Sikkelveld 27, NL-3993 RH Houten (NL). PLOMP, Adrianus [NL/NL]; Hulstweg 70, NL-1871 TJ Schoorl (NL). BOON, Gerhardus, Anthonius [NL/NL]; Haremakers 52, NL-1531 LC Wormer (NL). VAN SWIETEN, Roy [NL/NL]; Kerkstraat 18, NL-5253 AP Nieuwkuyk (NL).		<b>(74) Agent:</b> LAND, Addick, Adrianus, Gosling; Sweelinckplein 1, NL-2517 GK The Hague (NL).  <b>(81) Designated States:</b> AT (European patent), BE (European patent), CH (European patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB (European patent), GR (European patent), IT (European patent), LU (European patent), NL (European patent), SE (European patent), US.  <b>Published</b> <i>Without international search report and to be republished upon receipt of that report.</i>
<b>(54) Title:</b> INHALER DEVICES PROVIDED WITH A RESERVOIR FOR SEVERAL DOSES OF MEDIUM FOR INHALING, TRANSPORTING DEVICE, WHIRL CHAMBER		
<b>(57) Abstract</b>  <p>The present invention provides an inhaler device (1) for inhaling an aerosol in a desired dosage, comprising a housing (2) in which is received a reservoir (3) of powder or liquid, an inhaling piece (7) placed on the housing and means for transporting the powder or liquid from the reservoir to the inhaling piece in a dosage required for the aerosol. The transporting mechanism can be a spring loaded plunger (11) with a toroidal space along its walls, that is filled by the medication when the plunger is pushed down, and that brings the medication into a whirl mixing chamber (16, 55), when it is pushed upwards by the spring. In another embodiment the transport mechanism can be a worm (56), hand rotated, in order to transport medication from the reservoir into the whirl mixing chamber (16, 55). The whirl mixing chamber (55), activated by the patient's inhaling, has two feed channels (62-63), one to transport the medication into the chamber, the other to cross the first one at right angles to disrupt the flow and enhance medication mixing.</p>		

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**INHALER DEVICES PROVIDED WITH A RESERVOIR FOR SEVERAL DOSES  
OF MEDIUM FOR INHALING, TRANSPORTING DEVICE, WHIRL CHAMBER**

The present invention relates to inhaler devices, in particular inhaler devices with which several doses can be administered. With such inhaler devices an aerosol is administered as medicine to the lungs, particularly the  
5 alveolar zone, by inhalation through nose or mouth.

Existing systems typically provide a single dose of an aerosol, whereafter a capsule is thrown away, which is harmful to the environment. Inhaler devices, for instance for CNSLD patients, wherein at each inhalation a capsule is  
10 placed therein, are frequently used in practice.

Inhaler devices for several doses are still only commercially available on a limited scale. There are problems with these known inhaler devices in respect of their manageability and size, the required suction force on  
15 a mouth or nose piece and/or the accuracy of dosing.

Known inhaler devices for several doses are awkward to use and/or consist of a relatively large number of components, whereby manufacture becomes time-consuming and expensive. Such an inhaler device is known from EP-A-211595.  
20

A first aspect of the present invention provides an inhaler device for inhaling an aerosol in a desired dosage, comprising a housing in which is received a reservoir of powder or liquid, an inhaling piece placed on the housing and means for transporting the powder or liquid from the  
25 reservoir to the inhaling piece in a dosage required for the aerosol.

A second aspect of the present invention has for its object to obviate one or more of the above stated problems and provides a device for inhaling an aerosol, comprising:

30 - a reservoir for storing a supply of medium for inhaling;

- an inhaling piece for sucking air along a dose of medium for inhaling; and

- transporting means for transporting a dose of medium for inhaling out of the reservoir, wherein a whirl chamber is incorporated in the inhaling piece for taking up the medium into the indrawn air with only a small suction  
5 force.

The present invention provides an inhaler device that can be used in different positions. The operation of the inhaling piece, the transporting means and/or the whirl chamber are not adversely affected by the position of the  
10 inhaler device relative to the direction of the force of gravity.

The whirling and high speed of the air are advantageous in obtaining particles for inhaling of a sufficiently small diameter (for instance smaller than 7, 5 or 1  $\mu\text{m}$ ). The  
15 medium in the reservoir usually also comprises carrier material to cause the medium to flow easily, particularly from the reservoir to the whirl chamber where the particles for inhaling are then separated from the carrier particles (of usually greater diameter) by the shear forces generated by  
20 the air. Also in the case the medium for inhaling does not comprise any carrier material, shear forces have to be applied thereto, since such inhaling medium is composed of complexes of relatively large diameter, for instance greater than 7  $\mu\text{m}$ . For inhalation into the alveolar zone the  
25 particle diameter also has to be reduced. With both types of medium there normally remains a non-inhalable fraction of for example 20% by vol.

Transporting of the medium for inhaling preferably takes place by means of a screw or worm since, as has been  
30 found in tests, an accurate dose of medium can be transported herewith.

Further preferred embodiments relate to the desired whirling of the air and the compactness of the inhaler device; such embodiments are specified in claims 10-15.

35 In preference the inhaler device comprises two or more mutually interchangeable reservoirs with different medium. A patient then only needs to carry one inhaler device on his/ her person, even when (s)he has to inhale

different types of medium. Such reservoirs can be provided in simple manner with a bayonet fitting for coupling to the remaining part of the inhaler device according to the present invention.

5 Inhaler devices provided with a mixing chamber, wherein at each inhalation a capsule with a dose of medium is introduced, in addition to a reservoir for several doses of medium for inhaling are widely available, for instance for CNSLD patients. The medium for inhaling typically  
10 comprises a powder which during inhalation must be present in the air in a particular diameter of for instance less than  $10\mu\text{m}$ , or less than 7, 5 or  $1\mu\text{m}$ . To improve the transporting properties of the powder, carrier material can be incorporated therein with a particle diameter greater  
15 than the above mentioned diameter. Also when no carrier material is included in the powder, complexes of particles occur easily in the aerosol which have a diameter greater than above stated. Particles with a greater diameter than the above stated are undesirable in the aerosol as they  
20 cannot exert any medicinal effect but can still result in irritations of the bronchial tubes, oral cavity and/or pharynx.

A third aspect of the present invention provides an inhaler device for inhaling an aerosol, comprising:

- 25 - a suction piece for sucking in the aerosol;  
- a mixing chamber for mixing sucked in air and medium for taking up air; and  
- separating means for separating that fraction of the aerosol whereof the particles have a diameter greater  
30 than a predetermined value.

It will be apparent that the present invention is not limited to the case wherein the medium is in powder form. Use of the device according to the present invention is equally conceivable for vaporized (liquid) medium.

35 Further advantages, features and details of the present invention will be elucidated in the light of a description of preferred embodiments thereof with reference to the annexed drawing, in which:

Fig. 1 shows a view, partly in section and partly in perspective, of a preferred embodiment according to the present invention in closed situation;

Fig. 2 is the view of fig. 1 in the ready-for-use  
5 situation;

Fig. 3 shows a view, partly in section and partly in perspective, of the embodiment of fig. 1 and 2 for elucidation of several details thereof;

Fig. 4 shows a view of an element to be included in  
10 the embodiment of fig. 1-3;

Fig. 5 shows a partly broken away view in perspective of a second preferred embodiment of the inhaler device according to the present invention;

Fig. 6 is a view, partly in perspective and partly in  
15 section, of detail II of fig. 5; and

Fig. 7A and 7B respectively show elements which can be incorporated in the embodiment as shown in fig. 5 and 6; and

Fig. 8 shows a side view of a third embodiment,  
20 partly in section, of the inhaler device according to the present invention.

An inhaler device 1 (fig. 1-3) according to the present invention comprises a housing 2 in which a reservoir 3 of inhalable material, which is medicinal in the  
25 embodiment shown, is held in a compressed state. Placed on the housing 2 is an inhaling piece 7, for example joined thereto in a manner not shown with a snap-on connection, so that after the reservoir has been emptied the inhaling piece can be placed on a new reservoir. The inhaling piece 7 is  
30 intended for placing on nose or mouth in order to be then sucked on. Placed over the inhaling piece 7 is a removable closing cap 8 provided with a protruding pin 9.

As will be apparent particularly from fig. 2, when the closing cap 8 is removed, a plunger 11 is moved upward  
35 by means of the spring force of a second coil spring 12. The plunger 11 is provided with a recess between a top piece 13 and a bottom piece 14, wherewith a dose of powder can be transported in the desired dosage from the reservoir to a

mixing space 16. As is indicated with the arrows, when the opening 17 is sucked on, suction takes place through three channels, of which the channels 18 and 19 are visible in the figure, and via whirling of the air a good mixing of the powder and the air is obtained in the desired manner.

In preference the pin portion 9 of the closing cap 8 is provided with a tapering portion which fits into the conical opening 17 so that when the closing cap 8 is arranged the up and downward movable plunger 11 provided with a central channel 21 and the recess can be moved into the rest position shown in fig.1.

For guiding the powder to the recess in the plunger the housing 2 is preferably provided with an upper piece 22 provided with collar-like portion 23 which protrudes into the powder reservoir.

So that the powder-form material is carried well by the plunger, the latter is provided with a protrusion guided in a groove 24 that is arranged in the cylinder-shaped guiding 25 for the plunger, wherein this groove 24 causes the plunger to rotate slightly.

In a further embodiment of the present invention (not shown), a shaft 40 provided with wing-like elements 41 can be included at the centre line of the device shown in fig. 1-3. Preferably a rotating mechanism is provided such that for every dose shaft 40 is rotated and powder is stirred by elements 41 whereby the flow of the powder is improved. The rotating mechanism can correspond to such mechanism as used in a ballpoint-pen for rotating the writing element thereof.

The present inhaler device is suitable for giving a large number of doses and therefore for prolonged use. It can be manufactured from a comparatively small number of components, preferably of plastic.

A second embodiment an inhaler device 51 (fig.5) is provided with a part 52 (fig.5, fig.6) in which is received a reservoir 53 for medium for inhaling in addition to a transporting mechanism 54 for transporting the medium out of the reservoir to a whirl chamber 55. The material for inhaling comprises carrier particles which are of minor

importance in the effect on the bronchial tubes of a patient. These carrier particles are necessary however in order to prevent the medium M for inhaling from coagulating and thereby becoming barely transportable.

5 For transporting the medium M in doses of precise size a screw or worm 56 is preferably used which can be operated using a rotating knob 57. It has been found in tests that such a transporting mechanism is capable of transporting a medium M with an accuracy of less than 5% out  
10 of the reservoir 53 into the whirl chamber 55 at each revolution of the opening 58 away from and up to a closing member 59 for this opening.

The inhaler device is provided with an inhaling piece 11 for sucking in air via the nose or mouth of a patient  
15 along two feed channels 62 and 63 which are arranged in a peripheral wall 64 of the inhaler device. A flow of air, as designated with arrows  $F_1$ , carries the medium brought into the whirl chamber 55 under cover plate 65 along a guide means 66 and then collides with the air flow designated with  
20 arrow  $F_2$  which is drawn in along feed channel 63. With a comparatively small suction force great air speeds occur here, in addition to whirls when these air flows  $F_1$  and  $F_2$  collide with one another. Shear forces hereby occur which separate the particles with medicinal effect from the  
25 carrier particles which usually have a greater diameter than that of the medicinal particles.

The member 16 for guiding the air (fig.7A) is provided on the side facing the feed channel 62 with a rounded form, while the side facing the feed channel 63 is sharp-  
30 edged and the angle is formed by flat wall portions 67 and 68 so that the air flow  $F_2$  collides with the air flow  $F_1$  transversely.

In a further embodiment (not shown), the inhaler device according to the present invention is provided with a  
35 guide means 71 for guiding the air (fig.7B) partially similar to the guide means 66, but which is additionally provided with an air guide portion 72 rising in the direction of the inhaling piece 11 and preventing unwanted



air, as indicated with arrow  $F_3$  in fig. 1, on the side of the guide means 71 remote from the doses of medium for inhaling from passing into the inhaling piece 11. An inhaler device provided with such a guide means 71 therefore  
5 requires an even smaller suction force, which is particularly important in the case of children and older patients with lung disorders.

The inhaler device according to the shown and described embodiment has, among others, the following advantages:  
10       - the inhaler device is compact of structure and has a size such that it can easily be held in the hand;  
         - the inhaler device can be used in any desired position, with the inhaling piece horizontal or oriented upward or downward;  
15       - the inhaler device requires little suction force, while great shear forces are applied to the medium or powder so that the medicinal particles are released from the carrier particles.

A third embodiment of an inhaler device 81 (fig.8)  
20 according to the present invention comprises a schematically designated mixing chamber 82 in which a dosage for inhaling is mixed with air drawn into the mixing chamber 82 in a manner not shown. The inhaler device 81 can further be provided with a reservoir in which is received a supply of  
25 medium for inhaling, in addition to transporting means, likewise not shown, for transporting one dose of medium at a time out of this reservoir into the mixing chamber.

Coupled to the mixing chamber 82 is a suction piece 83 comprising an inlet channel 84, an outlet channel 85 and  
30 a collecting chamber 86. The suction piece 87 is sucked on by the patient via nose or mouth. A fraction of the aerosol, designated with arrow  $B_2$  whereof the particles have a comparatively large diameter, for example greater than 10, 7, 5 or 1  $\mu\text{m}$ , does not however reach the outlet channel 85  
35 of the mass of the particles. These particles from the fraction  $B_2$  are collected at the bottom of the collecting chamber 86 which must be emptied from time to time by releasing the cover 88.

With the inhaler device (third embodiment) according to the present invention now proposed and still to be realized in practice, the angle enclosed by the centre lines of the outlet channel 85 and the inlet channel 84 has a value of approximately  $60^\circ$ , that is, the change of direction amounts to roughly  $120^\circ$ . The inlet channel is initially envisaged as having a diameter of approximately 1 cm, the outlet channel as having a diameter of 0.8 cm and the inlet channel as having a length of about 5 cm. The preferred embodiment shown is preferably realized in plastic. The figure is drawn to scale so that other proposed dimensions can be derived therefrom.

The present invention is not limited to the preferred embodiment shown and described. The rights are determined by the claims following hereinafter.

## CLAIMS

1. Device for inhaling an aerosol, comprising:
  - a housing in which is receive a reservoir of powder or liquid,
  - an inhaling piece placed on the housing; and
  - 5       - means for transporting the powder or liquid from the reservoir to the inhaling piece in a dose required for the aerosol.
2. Inhaler device as claimed in claim 1, wherein the transporting means comprise a plunger which is provided with  
10       recess and which is movable reciprocally counter to the pressure of a spring.
3. Inhaler device as claimed in claim 1 or 2, wherein the reservoir is provided with powder.
4. Inhaler device as claimed in claim 1,2 or 3,  
15       wherein a piston and spring are incorporated in the housing for holding the content of the reservoir in compressed state.
5. Inhaler device as claimed in any of claims 1-4, wherein the transporting means are reciprocally movable by  
20       means of a closing cap for placing on the inhaling piece, wherein when this closing cap is removed, a dose is transported to the inhaling piece.
6. Inhaler device as claimed in any of claims 2-5, wherein the plunger is provided with protrusion for causing  
25       the plunger to rotate relative to the housing.
7. Inhaler device as claimed in any one of claims 2-6, in which rotatable stirring elements or wing-like elements extend in the recess.
8. Device for inhaling an aerosol, comprising:  
30       - a reservoir for storing a supply of medium for inhaling;
  - an inhaling piece for sucking air along a dose of medium for inhaling; and
  - transporting means for transporting a dose of  
35       medium for inhaling out of the reservoir, wherein a whirl

chamber is incorporated in the inhaling piece for taking up the medium into the indrawn air with only a small suction force.

5 9. Inhaler device as claimed in claim 8, wherein the transporting means comprise a screw or worm.

10. Inhaler device as claimed in claim 8 or 9 provided with a piston which is under spring pressure and in turn holds the medium for inhaling under a certain pressure.

10 11. Inhaler device as claimed in claim 8, 9 or 10, wherein the whirl chamber is embodied such that air drawn in through a first opening moves along the dose of medium for inhaling and subsequently collides with an air flow drawn in along a second opening, wherein a whirling is excited such that the active constituents of the medium are released to a  
15 sufficient extent with sufficiently small diameter.

12. Inhaler device as claimed in any of the claims 8-11, wherein a mouth or nose piece of the inhaling piece is disposed eccentrically of the centre line of the inhaler device.

20 13. Inhaler device as claimed in any of the claims 8-12, wherein a guide means for guiding the air flow is arranged in the vicinity of the centre of the inhaling piece.

25 14. Inhaler device as claimed in claim 13, wherein the guide means is provided with a rounded portion and with a sharp-edged portion.

15. Inhaler device as claimed in claim 13 or 14, wherein the guide means is provided with a guide portion for guiding the air flow upward to the mouth or nose piece.

30 16. Inhaler device as claimed in any of the claims 8-15 provided with two or more mutually interchangeable reservoirs with different medium.

35 17. Transporting device for transporting powder for pharmaceutical or cosmetic purposes, provided with a screw or worm.

18. Transporting device as claimed in claim 17, wherein the screw or worm protrudes through a reservoir for

the powder, wherein the powder in the reservoir is pressed by a piston standing under spring tension.

19. Whirl chamber for an inhaler device provided with air channels such that a first air flow is guided along medium or powder and a second air flow collides with the first air flow in substantially transverse direction.

20. Inhaler device for inhaling aerosol, comprising:  
- a suction piece for sucking in an aerosol;  
- a mixing chamber for mixing sucked in air and medium for taking up in the air; and

- separating means for separating that fraction of the aerosol whereof the particles have a diameter greater than a predetermined value.

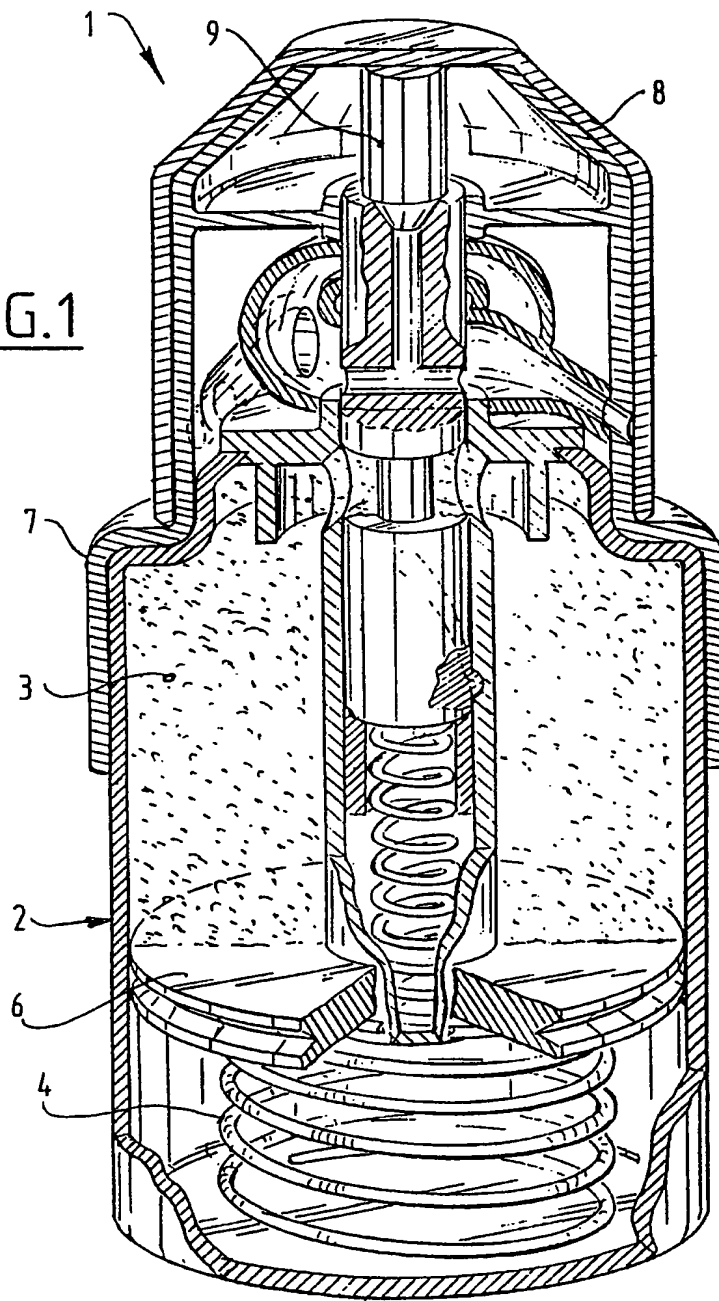
21. Inhaler device as claimed in claim 20, wherein the separating means comprise an inlet channel and an outlet channel, wherein the centre lines of inlet and outlet channels enclose an acute angle.

22. Inhaler device as claimed in claim 20 or 21, provided with a collecting reservoir for collecting the fraction with a relatively large particle diameter.

23. Inhaler device as claimed in claim 22, wherein the reservoir is provided with a releasable cover.

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FIG.1





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FIG.3

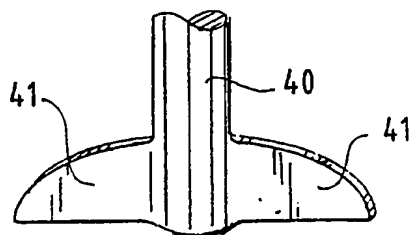
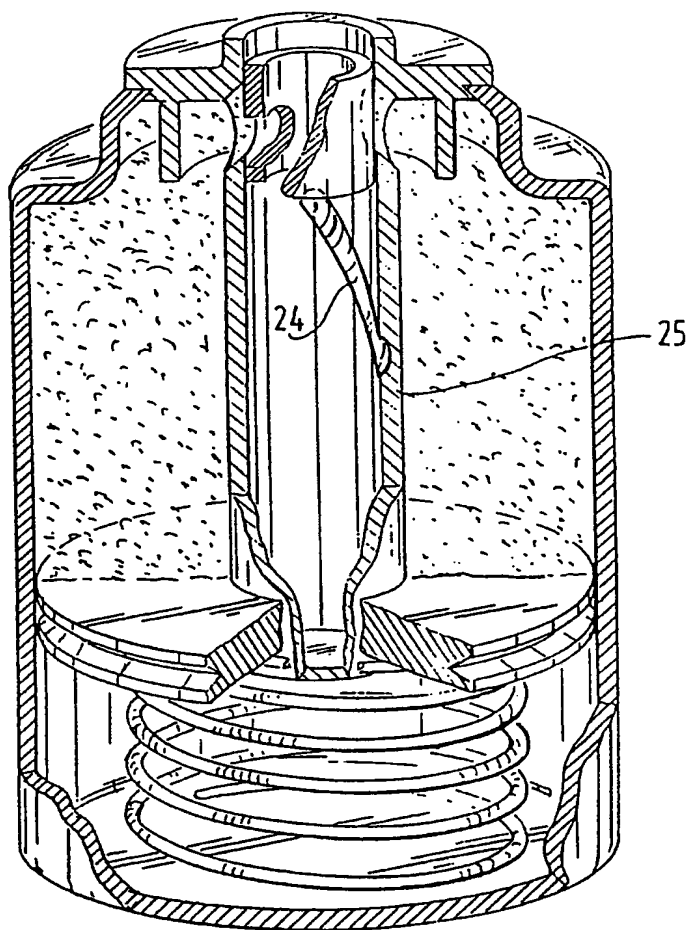
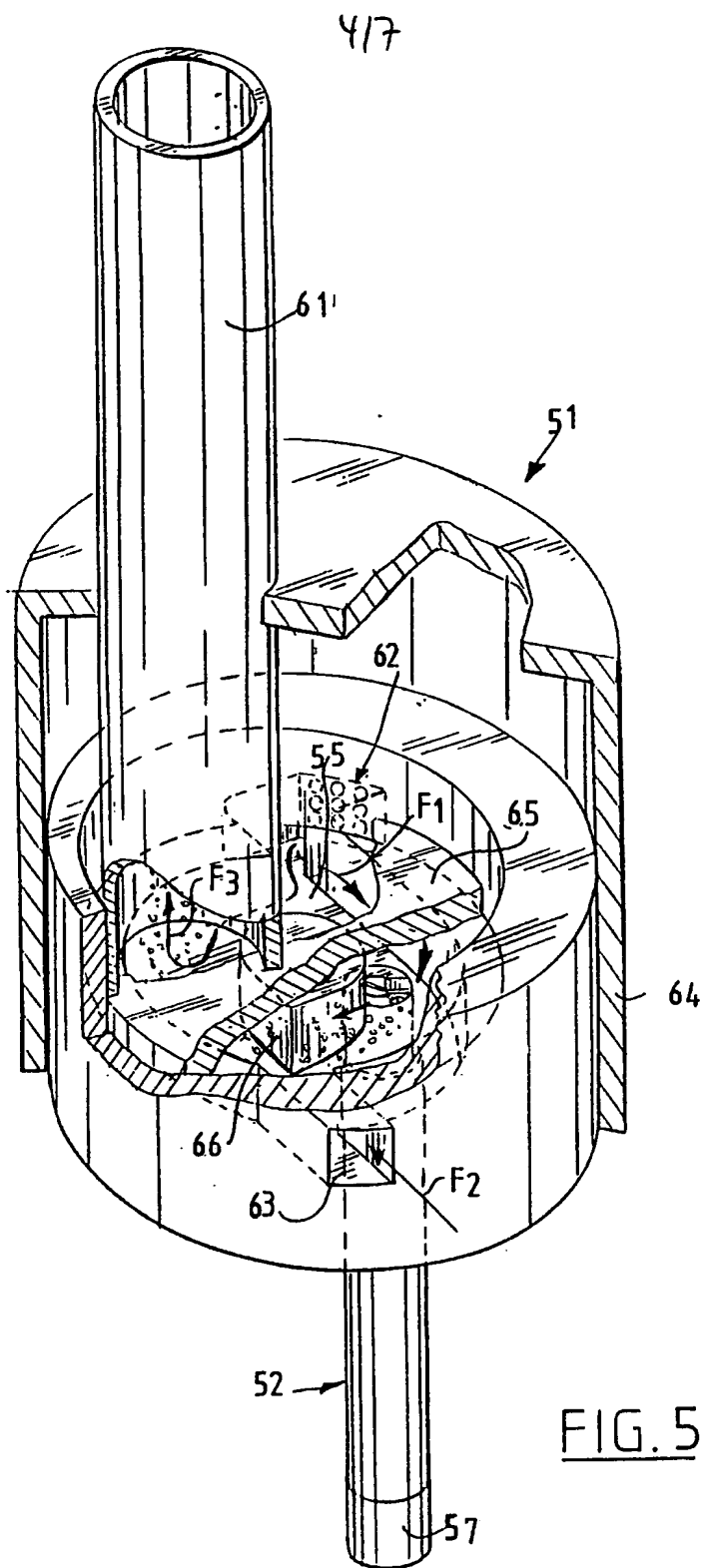
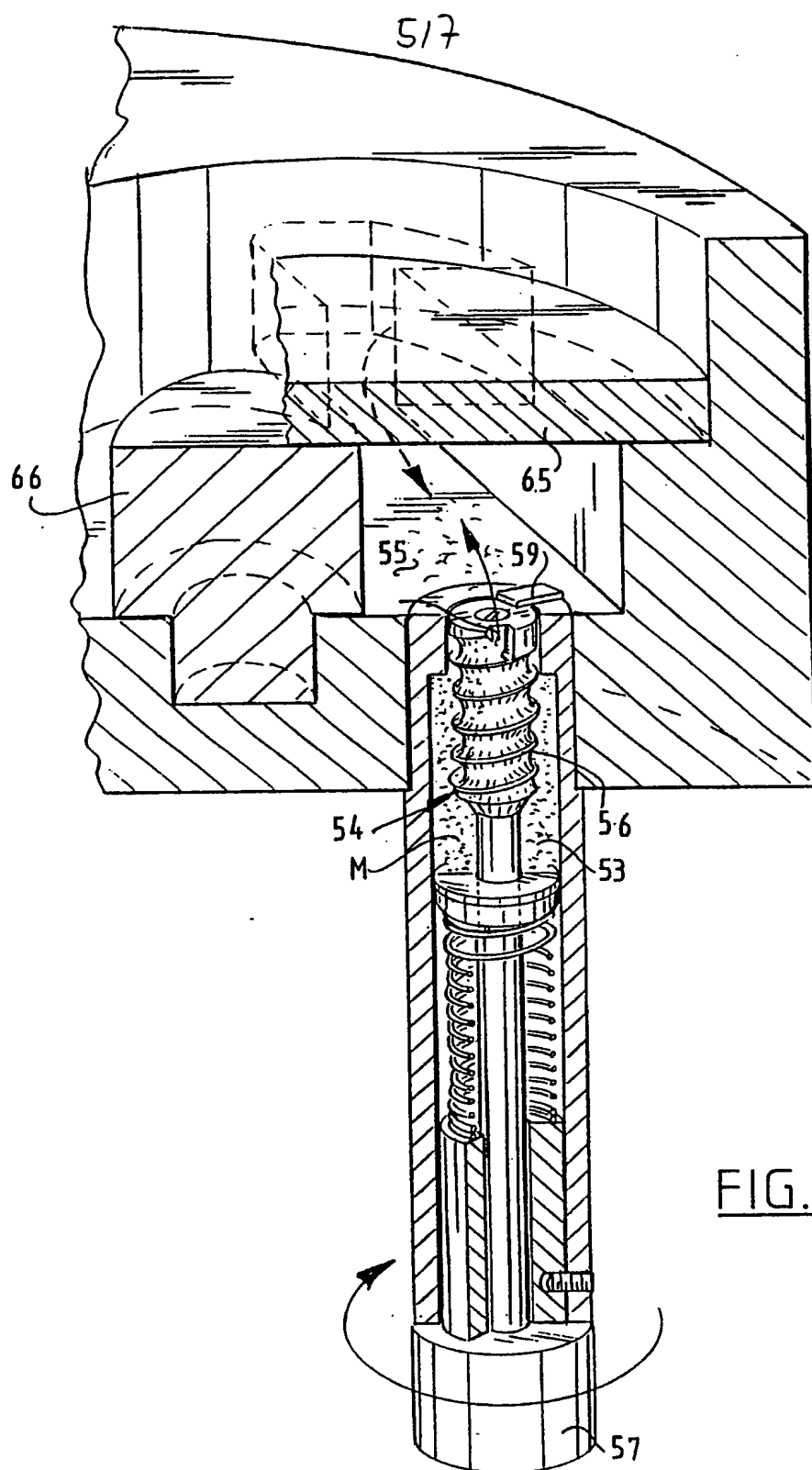


FIG.4







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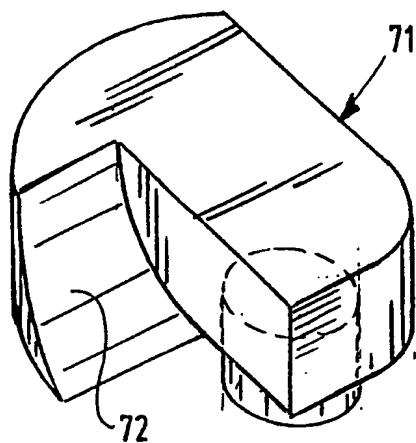


FIG. 7B

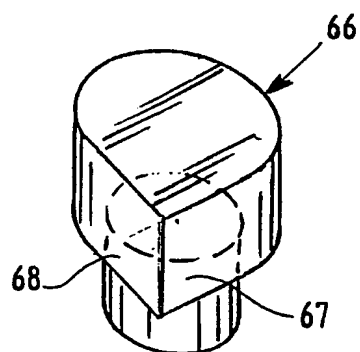


FIG. 7A

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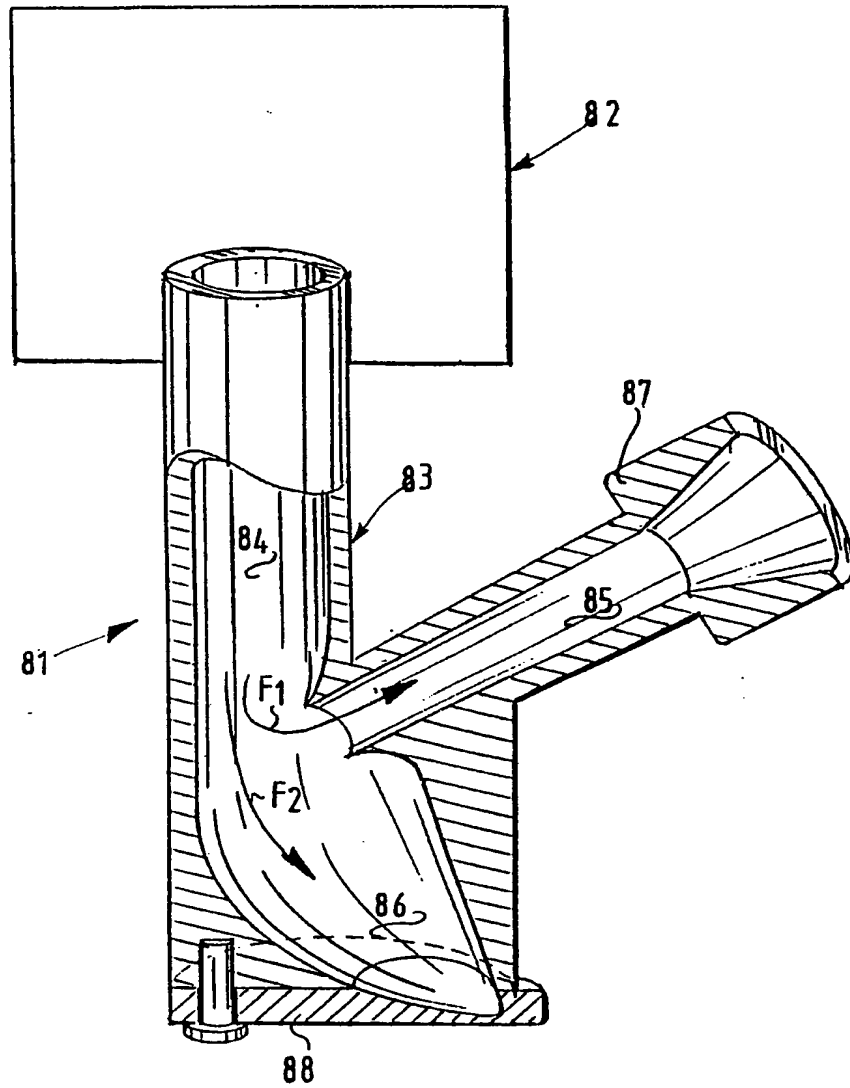


FIG. 8

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